

a final version of the draft Voluntary Guidance #213 of the Food and Drug Administration (entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GPI #209").

(b) REPORT BY GAO.—

(1) IN GENERAL.—Not later than 3 years after the publication of the final guidance described in subsection (a), the Comptroller General of the United States shall commence a study to evaluate—

(A) the voluntary approach used by the Food and Drug Administration to eliminate injudicious use of antimicrobial drugs in food-producing animals; and

(B) the effectiveness of the data collection activities conducted by the Food and Drug Administration regarding antimicrobial resistance.

(2) REPORT.—Not later than 1 year after commencing the study described in paragraph (1), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of such study.

**SA 2008.** Mrs. GILLIBRAND submitted an amendment intended to be proposed by her to the bill H.R. 3204, to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

### **TITLE III—PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS**

#### **SEC. 301. SHORT TITLE.**

This title may be cited as the "Cody Miller Initiative for Safer Prescriptions Act".

#### **SEC. 302. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.**

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505E the following:

#### **"SEC. 505F. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.**

"(a) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue regulations regarding the authorship, content, format, and dissemination requirements for patient medication information (referred to in this section as 'PMI') for drugs subject to section 503(b)(1).

"(b) CONTENT.—The regulations promulgated under subsection (a) shall require that the PMI with respect to a drug—

"(1) be scientifically accurate and based on the professional labeling approved by the Secretary and authoritative, peer-reviewed literature; and

"(2) includes nontechnical, understandable, plain language that is not promotional in tone or content, and contains at least—

"(A) the established name of drug, including the established name of such drug as a listed drug (as described in section 505(j)(2)(A)) and as a drug that is the subject of an approved abbreviated new drug application under section 505(j) or of an approved license for a biological product submitted under section 351(k) of the Public Health Service Act, if applicable;

"(B) drug uses and clinical benefits;

"(C) general directions for proper use;

"(D) contraindications, common side effects, and most serious risks of the drug, es-

pecially with respect to certain groups such as children, pregnant women, and the elderly;

"(E) measures patients may be able to take, if any, to reduce the side effects and risks of the drug;

"(F) when a patient should contact his or her health care professional;

"(G) instructions not to share medications, and, if any exist, key storage requirements, and recommendations relating to proper disposal of any unused portion of the drug; and

"(H) known clinically important interactions with other drugs and substances.

"(c) TIMELINESS, CONSISTENCY, AND ACCURACY.—The regulations promulgated under subsection (a) shall include standards related to—

"(1) performing timely updates of drug information as new drugs and new information becomes available;

"(2) ensuring that common information is applied consistently and simultaneously across similar drug products and for drugs within classes of medications in order to avoid patient confusion and harm; and

"(3) developing a process, including consumer testing, to assess the quality and effectiveness of PMI in ensuring that PMI promotes patient understanding and safe and effective medication use.

"(d) ELECTRONIC REPOSITORY.—The regulations promulgated under subsection (a) shall provide for the development of a publicly accessible electronic repository for all PMI documents and content to facilitate the availability of PMI."

#### **SEC. 303. PUBLICATION ON INTERNET WEBSITE.**

The Secretary of Health and Human Services shall publish on the Internet website of the Food and Drug Administration a link to the Daily Med website (<http://dailymed.nlm.nih.gov/dailymed>) (or any successor website).

### **AUTHORITY FOR COMMITTEES TO MEET**

#### **COMMITTEE ON FINANCE**

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session of the Senate on October 30, 2013, at 11 a.m., in room SD-215 of the Dirksen Senate Office Building, to conduct a hearing entitled "The Transatlantic Trade and Investment Partnership: Achieving the Potential."

The PRESIDING OFFICER. Without objection, it is so ordered.

#### **COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS**

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be authorized to meet during the session of the Senate on October 30, 2013, at 9:15 a.m., in room SD-430 of the Dirksen Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### **COMMITTEE ON INDIAN AFFAIRS**

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Indian Affairs be authorized to meet during the session of the Senate on October 30, 2013, at 2:30 p.m., in room SD-628 of the Dirksen Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### **COMMITTEE ON THE JUDICIARY**

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet during the session of the Senate on October 30, 2013, at 2:30 p.m., in room SD-226 of the Dirksen Senate Office Building, to conduct a hearing entitled "Nominations."

The PRESIDING OFFICER. Without objection, it is so ordered.

#### **COMMITTEE ON VETERANS' AFFAIRS**

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Veterans' Affairs be authorized to meet during the session of the Senate on October 30, 2013, at 2 p.m., in room SR-418 of the Russell Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### **SUBCOMMITTEE ON SECURITIES, INSURANCE, AND INVESTMENT**

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs Subcommittee on Securities, Insurance, and Investment be authorized to meet during the session of the Senate on October 30, 2013, at 10 a.m., to conduct a hearing entitled "The Jobs Act at a Year and a Half: Assessing Progress and Unmet Opportunities."

The PRESIDING OFFICER. Without objection, it is so ordered.

### **PRIVILEGES OF THE FLOOR**

Mr. LEVIN. Mr. President, on behalf of Senator MENENDEZ, I ask unanimous consent that Christopher Landberg, a detailee from the State Department and the Foreign Relations Committee, be granted floor privileges for the consideration of the nomination of Jacob Lew.

The PRESIDING OFFICER. Without objection, it is so ordered.

### **JOINT REFERRAL—RHEA SUN SUH NOMINATION**

Mr. REID. Mr. President, I ask unanimous consent as in executive session that the nomination of Rhea Sun Suh, of Colorado, to be Assistant Secretary for Fish and Wildlife, sent to the Senate by the President on October 30, 2013, be referred jointly to the Committee on Energy and Natural Resources and the Committee on Environment and Public Works.

The PRESIDING OFFICER. Without objection, it is so ordered.

### **CHIMP ACT AMENDMENTS OF 2013**

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 228, S. 1561.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1561) to amend the Public Health Service Act to improve provisions relating